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Shelley D. Minter

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EXAMINER

MARTIN, ANGELA J

ART UNIT

PAPER NUMBER

1795

NOTIFICATION DATE

DELIVERY MODE

06/30/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

uspatents@senniger.com

Office Action Summary	Application No. 10/617,452	Applicant(s) MINTEER ET AL.	
	Examiner Angela J. Martin	Art Unit 1795	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 March 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16, 18-77, 113-140 is/are pending in the application.
- 4a) Of the above claim(s) 1-5, 7, 9, 11, 36-41, 45, 27-35, 48-77 and 113-140 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6, 8, 10, 12-16, 18-26, 42-44, 46 and 47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

35 U.S.C § 112 Rejections

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 9-13, 15-20, 24, 26, and 30-37 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a bioanode with a solid electron conductor and distinct, solid layers of the other components, does not reasonably provide enablement or possession for a bioanode made of any electron conductor in any configuration. M.P.E.P. § 2163.02 state;

Whenever the issue arises, the fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed. See, e.g., *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997). Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was "ready for patenting" such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention.

It appears upon reading the specification that this invention is not solely the modified Nafion but also the specific layered structure of the bioanode. The Applicant

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does not appear to have possession of other electrode configurations other than the layered configuration presented in Figure 1 of the specification and those presented in the examples. It appears that the Applicant's invention requires a step wise reaction scheme where all the reagents must be in a specified proximity and location for the bioanode to work effectively. For example, as seen in Figure 1, the enzyme must first be oxidized which in turn oxidizes the substrate (bilirubin in the case of Figure 1), which then oxidizes the electron transfer mediator ($\text{Ru(bpy)}_3^{+2/3}$), which in turn then is reduced by the electron conducting material. It does not appear that the electrode will function if the layers are interchanged. For example if the electron transfer mediator was to proceed the enzyme instead of succeed the enzyme it is unclear in the specification if the electrode will function.

Furthermore, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The Applicant has not shown support that their design for a bioanode is compatible with all "electron conductors" available to one of ordinary skill in the art. In particular the term electron conductor is broad and Applicant's definition in the specification limits the electron conductor to only "a substance that conducts electrons". This type of definition includes liquid conductors that contain redox couples such as ferrocene in a scenario where liquid electron conductors or gel type electron conductors are used. In this scenario the bioanode with the components listed in the specification would be a homogenous mix and not the defined layers listed in the specification. Therefore while the Applicant has support for

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solid electron conductors with the components in specific layers and defined structure does not have support for a homogenous type bioanode as presented when the electron conductor is a liquid or gel. Furthermore this definition could include wires embedded or interlaced in the enzyme immobilization material (EIM) or graphite dust infused in the EIM as seen in conducting TEFLON (i.e. carbon impregnated TEFLON) none of which has support in the as filed specification. Therefore the claims 1-4, 9-13, 15-20, 24, 26, and 30-37 are rejection for exceeding their scope of enablement.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4, 9-13, 15-20, 24, 26, and 30-37 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are the final configuration of the layers of the bioanode that shows the inter-relationship and contact of the electron conductor (EC), enzyme (EZM), electron mediator (EM), oxidant (OX), electrocatalyst (ECAT), and enzyme immobilization material (EIM).

The claims include an electron conductor and the specification includes scenarios where the electron conductor is imperative to the operation of the biocathode for the dispensing of electrons to the ECAT, but it is unclear how ECAT or EM (Applicant's specification paragraph 11 and 12) actually contact or otherwise obtain the

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electron from the EC. The specification provides the very broad definition that the EC is "a substance that conducts electrons. The electron conductor can be organic or inorganic in nature as long as it is able to conduct electrons through the material". While the Applicant provides examples of solid conductors such as stainless steel or metal oxides, these examples are not limiting. This broad definition of EC can include liquid conductors as well as solid conductors. This further confounds the relationships of the various components since while the EZ is immobilized on the EIM, it is unclear how the other components such as the EM and ECAT of the various cathodes are transported or contact the EIM to complete the reactions of the bioanodes in a situation where the bioanode incorporates a liquid or gel-type conductor such as an salt saturated agarose gel that contains a redox couple such as ferrocene that can carry an electron. Furthermore this definition could include wires embedded or interlaced in the enzyme immobilization material (EIM) or graphite dust infused in the EIM as seen in conducting TEFLON. Furthermore the layered relationship of the materials presented in the specification is not limited in the claims. Considering broadly the EC, EM, ECAT and EIM that immobilizes the enzyme can be a homogenous mixture and not layers. Therefore the claims 1-4, 9-13, 15-20, 24, 26, and 30-37 are rejection for being indefinite.

Response to Applicant's Arguments—Double Patenting

In the response submitted by the Applicant, the nonstatutory double patenting rejection of claims 1-4, 15, and 25 over claims 1-27, 29-35, 42-44 of copending Application No. 10/931147 were considered.

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The Applicant argues that the enzyme immobilization material of '452 is not conducting which is a limitation of the current application. However the Examiner notes that the enzyme mobilization material of the current application comprises the stabilized enzyme and an electrocatalyst. The enzyme immobilization material of '452 also comprises an enzyme and electrocatalyst. Without further limitations to differentiate the structures of these enzyme immobilization materials they contain the same components and thus are the same material and as such claims remain obvious over each other in this respect.

Also the Applicant argues that the enzymes of the two inventions differ. However claim 23 of '452 expressly states the enzyme can be an oxidoreductase. The bioanode of the current invention comprises the enzyme oxidase and the enzyme in '147 is of the family of oxidoreductase. Therefore the non-statutory double patenting for 6, 8, 10, 12-26, 42-44, 46, 47 remains.

Response to Applicant's Arguments— 35 U.S.C § 103

In the response submitted by the Applicant, the 35 U.S.C § 103 (a) rejection of claims 6, 8, 10, 12, 42-44, 47 over Karyakin et. al. were considered but not found persuasive.

The Applicant argues that "Karyakin et al. used glucose oxidase and aldehyde dehydrogenase in the electrons and neither of these enzymes react with a reduce form of an electron mediator and an oxidant to produce an oxidized form of the electron mediator and water as required of part (b) of claim 2" (Emphasis added). The key phrase in this limitation is "at least one enzyme capable of reacting with a reduced form of an electron mediator and an oxidant". The limitation, as written does not provide a sequence of reactions such as a step-wise reaction path or order of operation. It does not exclude scenarios such as the reduced electron mediator can react with the oxidant first, forming an oxidized electron mediator, then with the enzyme. It also does not exclude scenarios that the oxidant can react with the enzyme then the electron mediator or visa versa. One of ordinary skill in the art would recognize that glucose oxidase (Gox)

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requires the cofactor such as flavin adenine dinucleotide (FAD) as supported by Advanced Enzymes (see Glucose Oxidase) which is well known by one of ordinary skill in the art as a common EM in biological systems. Karyakin et al. uses the cofactor NAD/NADH (Karyakin, page 4336, col 2, Experimental Section) which one of ordinary skill in the art would recognize is an art defined equivalent cofactor that serves the same purpose (see M.P.E.P. § 2144.06 II). In the reaction diagram of glucose oxidase pathway provided the reduced form of the EM reacts with the oxidant (in this case O₂) and produces the oxidized EM and hydrogen peroxide. The oxidized form of the EM then reacts with the enzyme. One of ordinary skill in the art would recognize that hydrogen peroxide rapidly degrades to water. This scenario was mentioned in the above and thus meets the limitation (b) for claims 1-4.

Also the Applicant argues that Karyakin et al. does not teach "the stabilized enzyme retaining at least about 75% of its initial catalytic activity for at least about 30 days while continuously reacting with electron mediator". The use of "at least about" while not indefinite has a larger scope than the numbers that confine the enzyme activity or the duration the enzyme activity is maintained. As such the limitations of the stabilized enzyme retaining at least about 75% of its initial activity for at least about 30 days" are much broader than the numbers specify (see M.P.E.P. § 2173.05(b) A). The Applicant's specification does not teach a specific range or provide guidance for the Examiner to limit ranges modified by "at least about". Furthermore these limitations carry little patentable weight since enzyme activity and longevity are heavily dependant on numerous variable factors such as temperature, buffer composition, substrate

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availability etc. In summary while this limitation does not render the claim indefinite the Examiner must assume that any sustained enzyme activity meets the limitations of "the stabilized enzyme retaining at least about 75% of its initial catalytic activity for at least about 30 days while continuously reacting with electron mediator". Therefor since Karyakin et. al. shows their biocatalysts are stabilized (Karyakin Figures 3 and 5) they meet the broad limitations presented in the claims concerning stability.

The Applicant further argues that results shown by the Applicant indicate that the Gox immobilized in Nafion results in an enzyme activity lower than the enzyme freely disbursed in solution. While this result is interesting it has little bearing on how the prior art relates to the claims considering the broad interpretation of the limitations "at least about" as discussed above in detail. Therefore the rejection stands and is repeated below.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 17-22 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Karyakin et. al., (Anal. Chem., 1996, 68, 4335-4341).

Karyakin discloses an electrode comprising glassy carbon electrodes (pg 4337) coated with Nafion (enzyme immobilization material) and poly(methylene green) (electrocatalyst). The enzyme-Nafion complex was made by mixing the enzyme suspension with Nafion solution and by syringing an appropriate amount of the enzyme

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polyelectrolyte complex to the target surface and allowing the solvent to evaporate. The Examiner notes that the cocasting of Nafion and the enzyme allows for stabilization of the enzymes.

Karyakin discloses a bioelectrode, but does not expressly disclose that it is a biocathode. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use Karyakin's electrode as either a biocathode or a bioanode or both in a bio fuel cell depending on if it were to yield or gain electrons. Being a cathode, it necessarily is capable of gaining electrons from the electron conductor to produce a reduced form of the electrocatalyst that is capable of reacting with an oxidized form of the electron mediator to produce a reduced form of the electron mediator and an oxidized form of the electrocatalyst. Therefore the references listed above renders obvious claims 1-4, 9, 11-13.

In the response submitted by the Applicant, the 35 U.S.C § 103 (a) rejection of claims 17-22 over Karyakin et. al. in view of Jin (Mikrochim. Acta, 112, 71-75 (1993)) were considered but not found persuasive.

The Applicant appears to argue that that the process used by Jin et al. to modify the electrode would produce a significantly different product than that of the current invention. However it was not specifically pointed out to the Examiner how this process of Jin fails to meet the limitations of claim 10. Also claim 10 does not specifically limit the extent the hydrophobic cations are exchanged with the protons with the sulfonate

groups so this line of argument appears to not be commensurate with the scope of the claims.

Furthermore the Applicant argues that Jin fails to remedy the failings of Karyakin et al. in terms of the limitation "the stabilized enzyme retaining at least about 75% of its initial catalytic activity for at least about 30 days while continuously reacting with electron mediator" as discussed above in the rejection with Karyakin et al. alone. However as discussed above Karyakin et al. does not require any support to meet this limitation given the broad interpretation of the limitation "at least about" as discussed previously in the rejection of Karyakin et al. alone (see page 6-7 of this Office Action). Therefore the rejection stands and is repeated below.

Claims 17-22 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Karyakin et. al, further in view of Jin (Mikrochim. Acta, 112, 71-75 (1993)).

Karyakin teaches all the elements of claim 17. Karyakin does not teach Nafion® modified with quaternary ammonium bromides. Jin teaches an electrode modified with Nafion and methyl viologen with immobilized urate oxidase. Jin teaches that catalytic reduction of dissolved oxygen on the Nafion-methyl viologen electrode results in fast and sensitive dissolved oxygen determination (pg 71 and 74). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the Nafion of Karyakin with methyl viologen for the benefit of fast and sensitive dissolved oxygen determination. Therefore the references listed above renders obvious claims 10 and 15.

In the response submitted by the Applicant, the 35 U.S.C § 103 (a) rejection of claims 6, 13-16, 23-26 over Zawodzinski et. al., (Electroanalysis, 1995 7(11), 1035-1040), in view of Gregg (U.S. Patent # 5264105) were considered but not found persuasive.

The Applicant argues as above that Zawodzinski et al. and Gregg do not teach the limitation "the stabilized enzyme retaining at least about 75% of its initial catalytic activity for at least about 30 days while continuously reacting with electron mediator". However as mentioned above in the rejections with Karyakin, the use of the limitation "at least about" for a broader interpretation than the numbers specified in claim and that the Examiner must assume that any sustained enzyme activity meets the above limitations (see page 6 and 7 of this Office Action). Therefore since Zawodzinski et al. and Gregg do teach sustained enzymatic activity they do meet the limitation of enzyme stability. Therefore the rejection stands and is repeated below.

Claims 16, 13-16, 23-26 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Zawodzinski et. al. (Electroanalysis, 1995 7(11), 1035-1040) in view of Gregg (US 5264105).

Zawodzinski discloses an electrode comprising Nafion (electron conducting enzyme immobilization material), glucose oxidase (enzyme), and carbon supported platinum. See Abstract. The conductive substance can be either carbon glass or carbon paper (applicant's claims 11-13). Zawodzinski discloses that the electrode

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responds rapidly and is stable over a long period (90% activity after more than half a year). See Abstract.

Zawodzinski discloses a bioelectrode, but does not expressly disclose that it is a biocathode. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use Zawodzinski's electrode as either a biocathode or a bioanode or both in a bio fuel cell depending on if it were to yield or gain electrons. Being a cathode, it necessarily is capable of gaining electrons from the electron conductor to produce a reduced form of the electrocatalyst that is capable of reacting with an oxidized form of the electron mediator to produce a reduced form of the electron mediator and an oxidized form of the electrocatalyst.

Zawodzinski discloses platinum as catalyst, but it is noted that it is not capable of gaining electrons from the electron conductor. Gregg teaches a redox compounds, or redox centers. Transition metal complexes with organic ligands such as bipyridine are preferred as redox centers because of their chemical stability and various oxidation states and their fast electron transfer kinetics. Examples of such complexes include polypyridine complexes of di- or trivalent osmium ions. The term "redox compound" is used herein to mean a compound that can be oxidized and reduced. The redox compound may have one or more functions that are reducible and oxidizable. Further, the term "redox compound" means a compound which contains one or more redox centers, "redox center" meaning a chemical function that accepts and transfers electrons (3:33-45). It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute Zawodzinski's platinum with Gregg's

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osmium²⁺(2,2'bipyridine)₃ for the benefit of providing fast chemical reaction of the analyte material.

Gregg discloses that in Example 2 that the concentration of osmium bis bipyridine chloride is 456 mg/100 ml EtOH, or 0.01 M (see 7: 65). The calculation is based on the molecular weight of osmium bis bipyridine chloride as 444 g/mol. Gregg does not disclose the concentration as claimed in claims 34-37. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to vary the concentration of the transition metal complex to meet the electron transfer kinetics of the electrode. It has been held by the courts that where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. In re Swain et. al., 33 CCPA 1250, 156 F.2d 239, 70 USPQ 412. Therefore the references listed above renders obvious claims 1-4, 9, 11-13, and 30-32, 34-37.

The Applicant argues that the three references above do not teach the limitation "the stabilized enzyme retaining at least about 75% of its initial catalytic activity for at least about 30 days while continuously reacting with electron mediator". However this limitation was already addressed by the rejection of Zawodzinski et al. in view of Gregg (see page 10 of this Office Action for review) and applies to this rejection as well. Therefore the rejection stands and is repeated below.

Claims 24 and 26 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Zawodzinski et. al. (Electroanalysis, 1995 7(11), 1035-1040), in view of Gregg (US 5264105) as applied to claim 2 above, and further in view of Khan (US 2004/0217016).

Zawodzinski modified by Gregg teaches all the elements of claim 2 and is incorporated herein. Zawodzinski discloses that the redox enzyme is glucose oxidase and does not disclose that the redox enzyme is bilirubin oxidase. However, Khan discloses that the specific enzyme present depends on the particular analyte for which the electrochemical test is designed to detect, which includes bilirubin oxidase [0029]. Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use bilirubin oxidase should the analyte be bilirubin, as bilirubin oxidase is capable of oxidizing bilirubin when used as the analyte. In this case, Khan's teaching of selecting a specific enzyme in the reaction area depending on the particular analyte demonstrates that compatibility is required when choosing enzyme-analyte systems. As such, it is contended that they both are fully compatible. Therefore the references listed above renders obvious claims 24 and 26.

Zawodzinski modified by Gregg teaches all the elements of claim 1. Zawodzinski modified by Gregg does not teach ruthenium²⁺(2,2'bipyridine)₃. Gregg teaches a bipyridine with a transition metal osmium (3:40-45), but does not disclose that the transition metal is ruthenium. Heller teaches a bipyridine compound of osmium or ruthenium as redox species [0040]. It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute ruthenium for osmium because osmium and ruthenium are both Group VIIIA transition metals which enable electron transfer for completing catalytic activities in electrodes. It has been recognized

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that both osmium and ruthenium are art recognized equivalents as electron transfer species. Therefore the references listed above renders obvious claim 33.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Angela J. Martin whose telephone number is (571)272-1288. The examiner can normally be reached on Monday-Friday from 10:00 am to 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patrick Ryan can be reached on 571-272-1292. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Angela J. Martin/
Examiner, Art Unit 1795